HairMax LaserComb

Advanced 7, Lux 9 and Professional 12

Males

510(k) # 103368

FDA Clearance to Market

April 6, 2011

APR - 6 2011

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for Lexington International, LLC HairMax LaserComb Advanced 7, HairMax LaserComb Lux 9 and HairMax LaserComb Professional 12 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

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Date of Submission: November 16, 2010

Proprietary Name: HairMax LaserComb Advanced 7, HairMax LaserComb Lux 9 and HairMax LaserComb Professional 12

Common Name: Lamp, non-heating, for promotion of hair growth

Regulatory Class: II

Product Codes: OAP

Predicate Device(s): Lexington International, LLC HairMax LaserComb K060305 and K093499

Device Description:

Substantially equivalent to the HairMax LaserComb (K060305, K093499), the modified HairMax LaserComb Advanced 7, HairMax Lux 9 and HairMax Professional 12 are hand-held low level laser devices that emits laser light with the intention to promote hair growth. The devices provide distributed laser light to the scalp while the comb teeth simultaneously part the user's hair to ensure the laser light reaches the user's scalp. HairMax LaserComb Advanced 7, HairMax Lux 9 and HairMax Professional 12 replace the cleared version's

single beam laser and beam splitting reflector with a circuit board containing seven, nine, or twelve laser diodes, respectively.

Intended Use:

The HairMax LaserComb Advanced 7, HairMax Lux 9 and HairMax Professional 12 are indicated to treat androgenetic alopecia, promote hair growth and help prevent further hair loss in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and Fitzpatrick Skin Types I to IV.

Technological Characteristics

The HairMax LaserComb Advanced 7, HairMax Lux 9 and HairMax Professional 12 consist of a hand-held low level laser devices that promotes hair growth. The device provides distributed laser light to the scalp while the device's comb teeth simultaneously part the user's hair to ensure the laser light reaches the user's scalp. When in use, the device emits a beep (9 and 12 laser models) or vibration (7 laser model) every four seconds to notify the user to move the device to a new section of the scalp.

Performance Testing

Testing to IEC 60601-1 and 60601-1-2 confirm the device's adherence to LVD electrical and EMC safety requirements. Testing to IEC 60825 confirm the laser classification to be Class 3R, same as predicate devices.

Clinical Testing

Two randomized, double-blind, controlled, multi-center clinical trials were conducted to confirm the performance of the subject devices. These studies confirm that the subject devices are expected to provide an effective dose rate to promote hair growth in males with androgenetic alopecia who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and Fitzpatrick Skin Types I to IV with safety and effectiveness outcomes substantially equivalent to those of the predicate devices.

Additionally, a study was conducted to validate the HairMax LaserComb User Manual (Copyright 2009) for the Lux 9, Professional 12 beam unit and confirm usability. Participants in the study were given access to the HairMax LaserComb and the User Manual under controlled conditions. Based on the study outcomes, the device and manual were validated within a sample population that could potentially desire to use the HairMax LaserComb.

Substantial Equivalence

The HairMax LaserComb Advanced 7, HairMax Lux 9 and HairMax Professional 12 are as safe and effective as the predicate devices. The HairMax LaserComb Advanced 7, HairMax Lux 9 and HairMax Professional 12 have the same intended use of promoting hair growth as the predicate devices. The subject devices have the same general indications, *i.e.*, treating androgenetic alopecia, and the same specific indication of promoting hair growth in males with androgenetic alopecia who have Norwood-Hamilton Classifications of I to V patterns of hair loss as the predicate devices.

Except for modifications to the laser delivery method and slight increases in laser output, the HairMax LaserComb Advanced 7, HairMax Lux 9 and HairMax Professional 12 is identical in technological characteristics as the HMLC as cleared in K060305 and K093499, including its red laser wavelength, its comb component, its instructions for use and its audible or vibrating timer. The modification to the HairMax LaserComb Advanced 7, HairMax Lux 9 and HairMax Professional 12 does not change the intended use of the product nor does it affect the products fundamental scientific technology. Therefore this change does not raise new questions of safety or effectiveness. This was also demonstrated in randomized, double-blind, control clinical studies evaluating changes in terminal hair-count in the evaluation zone, as well as usability studies to validate instructions for use, confirm that device modifications do not affect the safe and effective use of the devices when compared to the predicates.

For those reasons, the HairMax LaserComb Advanced 7, HairMax Lux 9 and HairMax Professional 12 satisfy FDA's substantial equivalence with respect to both the intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Lexington International, LLC
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APR - 6 2011

Re: K103368
Trade/Device Name: HairMax LaserComb Advanced 7, HairMax LaserComb Lux 9 and HairMax LaserComb Professional 12
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: January 26, 2011
Received: March 15, 2011

Dear Mr. Uldriks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: To be assigned

Device Name: HairMax LaserComb Advanced 7, HairMax LaserComb Lux 9 and HairMax LaserComb Professional 12

Indications for Use:

The HairMax LaserComb Advanced 7 is indicated to treat androgenetic alopecia, promote hair growth and help prevent further hair loss in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and Fitzpatrick Skin Types I to IV.

The HairMax LaserComb Lux 9 is indicated to treat androgenetic alopecia, promote hair growth and help prevent further hair loss in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and Fitzpatrick Skin Types I to IV.

The HairMax LaserComb Professional 12 is indicated to treat androgenetic alopecia, promote hair growth and help prevent further hair loss in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and Fitzpatrick Skin Types I to IV.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for max

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103368

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